

### **REMARKS**

Applicants have amended Claims 1, 9, 44-47, and 51, and have cancelled Claims 2, 6, 42-43, and 48-49. Enabling support for the amendments can be found in the application as filed, and therefore no new matter is contained in the amendments. Reconsideration of the present application and allowance of resulting Claims 1, 3-5, 7-14, 18-29, 44-47 and 50-51 is respectfully requested in view of the amendments and following remarks.

#### **I. Objection to the Priority Claim**

Applicants have amended the first paragraph of the specification above to correctly recite the priority claims for the instant application. Applicants attach herewith a new oath or declaration executed by the Applicants properly claiming priority to U.S. Application Serial No. 08/843,205 under 35 U.S.C. §120, rather than under 35 U.S.C. §119(a)-(d). Applicants submit that the amendment and the new declaration perfect the priority claim and that the objection should be withdrawn.

#### **II. Duplicate Claims**

The Office Action stated that Claim 43 is substantially the same as Claim 50. Claim 43 has been cancelled. Applicants submit that the cancellation of Claim 43 makes the rejection moot and that the rejection should be withdrawn.

#### **III. Sequence Listing Objection**

Applicants have amended the paragraph on page 68 to add a reference to sequence identification numbers. The MPEP at §2422.03 states “Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as “residues 14 to 243 of SEQ ID NO:23” is permissible and the fragment need not be separately presented in the “Sequence Listing.”” Applicants submit that the amendment reciting “residues 128-133 of SEQ ID NOs:4, 5, and 11, respectively” satisfies the sequence identification requirements, and that the objection should be withdrawn.

**IV. Claim Rejections under 35 U.S.C. § 112, second paragraph**

The Office Action rejects Claim 2-4, 6, 9, 44-47, and 51 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 6 have been cancelled. Applicants submit that the cancellation of these claims makes the rejection under 35 U.S.C. § 112, second paragraph moot as against Claims 2 and 6.

The Office Action rejects Claims 3-4 and 51 asserting that the term “stringent conditions” is subjective. Applicants have amended Claims 1 and 51 to recite a specific condition for the stringent conditions for hybridization as provided on page 31 of the instant specification, and submit that this amendment overcomes the rejection.

The Office Action rejects Claim 9 for reciting a polypeptide that can be SEQ ID NO:3, where SEQ ID NO:3 is a polynucleotide sequence and not a polypeptide sequence. Claim 9 has been amended to claim SEQ ID NO:5 rather than SEQ ID NO:3, and Applicants submit that this amendment overcomes the rejection.

The Office Action submits that Claims 44-47 are vague in that they recite nucleotide numbers of 1 to 1291, 1 through 1513, 3722 to 6235, and 4302 to 6235 of SEQ ID NO:7, where SEQ ID NO:7 only contains 232 nucleotides. Claims 44-47 have been amended to recite SEQ ID NO:1 rather than SEQ ID NO:7, and Applicants submit that these amendments overcome the rejections.

For at least the foregoing reasons, Applicants respectfully request reconsideration and removal of the rejections and allowance of Claims 3-4, 9, 44-47, and 51.

**V. Claim Rejections under 35 U.S.C. § 112, first paragraph**

Claims 1, 6-8, 11-14, 18-29, 43-47, and 50-51 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Claim 43 has been cancelled, and the rejected is therefore moot as to that claim.

Claim 1 of the present application has been amended to incorporate the limitations of Claim 2, such that Claim 1 now refers to nucleic acid sequences that (a) encode an insect JHR/bHLH polypeptide and (b) hybridize under stringent conditions to well-defined nucleic acid sequences. The terms “insect JHR/bHLH polypeptide”, “hybridization” and “stringent conditions” are explained in detail in the instant specification at, for example, page 8, line 25 et seq., page 28, line 34 et seq., and page 30, line 33 et seq. These amendments narrow claim 1 and also narrow the remaining dependent claims, 7-8, 11-14, 18-29, 44-47, and 50-51.

Using the novel sequences of the present invention, one of ordinary skill in the art can easily determine homologous/functional equivalents of JHR/bHLH from other insect species using the disclosed sequences of the invention as proven in hybridization experiments carried out in stringent conditions as outlined. An exemplary method of determining such equivalents is stated in the instant specification at page 29, line 5 et seq. and page 53, line 30 et seq. Determining equivalents based on hybridization is a routine procedure for one of ordinary skill in the art.

The respective isolated nucleic acid sequences will share a high degree of homology with the nucleic acid sequences of the present invention if they hybridize under stringent conditions with the insect JHR/bHLH polypeptide encoding nucleic acid sequences claimed in the present invention. This provides strong evidence to one of skill in the art that these sequences will also encode a functional equivalent of the *D. melanogaster* bHLH/JHR.

After isolating the full length sequences from other species, the skilled artisan can clone the gene, express the protein, and test whether the expressed protein is able to bind JH using the teachings of the present invention.

An example for isolating functional equivalents of known *Met*-JHR sequences for one of ordinary skill in the art is provided using the *D. erecta* sequence fragment as defined in SEQ ID NO:7, which is nearly identical to the *D. melanogaster* nucleic acid sequence. The *D. erecta* and *D. melanogaster* sequences have only minor deviations in sequence, as shown in Figure 5 of the present specification. There are no significant differences between SEQ ID

NO:1 and SEQ ID NO:7. This demonstrates that SEQ ID NO:7 clearly encodes a bHLH/JHR.

The Examiner states that the remaining coding and regulatory sequences for SEQ ID NO:7 must be obtained empirically. However, the isolation of a full length gene is a routine procedure for one of ordinary skill in the art with the knowledge of the nucleic acid sequences disclosed in the present invention. As such, it would be routine for a person skilled in the art to isolate and sequence the full-length clone of SEQ ID NO:7.

Applicants respectfully submit that the amendment of Claim 1 to require that the claimed nucleic acid sequences hybridize to known *D. melanogaster* Met-JHR sequences along with the arguments presented herein establish that the claims of the instant application satisfy the written description requirement. For at least the foregoing reasons, Applicants respectfully request reconsideration and removal of the rejection and allowance of Claims 1, 7-8, 11-14, 18-29, 44-47, and 50-51.

## **VI. Double Patenting Rejections**

The Office Action rejected Claims 42, 48, and 49 under 35 U.S.C. §101 as claiming the same invention as that of claims 1-3 of prior U.S. Patent No. 6,326,165. Claims 42, 48, and 49 have been cancelled. Applicants submit that the cancellation of these claims moots the same-type, statutory, double patenting rejection.

Claims 1-14, 43, and 50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 4-24 of U.S. Patent No. 6,326,165. The Office Action states that “claims 1, 4-24 fall entirely within the scope of claims 1, 6-14, 43 and 50, in other words, claims 1, 6-14, 43, and 50 are anticipated by claims 1, 4-24 of the ‘165 patent. . . With regard to SEQ ID NO:7, the instant claims differ from the patented claims . . . only in the recitation of SEQ ID NO:7 in the context of open language rather than closed language. . . With regard to instant claims 2-5, the claims. . . read on polynucleotides which are identical to SEQ ID NOs: 1-3, 6 or sequences which encode SEQ ID NOs:4-5 and hence are anticipated by the claims in the ‘165 patent.”

Claims 2, 6, and 43 have been cancelled and therefore the rejection is moot with respect to these claims. Applicants respectfully submit that the amendments attached hereto overcome the obviousness-type double patenting rejections for Claims 1, 3-5, 7-14, and 50.

## **VII. Claim Rejections under 35 U.S.C. §102**

Claims 1 and 6-8 were rejected under 35 U.S.C. § 102 as being anticipated by Turner *et al.* (Archives of Insect Biochemistry and Physiology, Vol. 30, 1995, pp. 133-147). Claim 6 has been cancelled, and it is submitted that the rejection is moot with respect to that claim. The Office Action states that Turner *et al.* “discloses isolated cosmids that contain the Met-JHR gene from the fruit fly *Drosophila melanogaster*. . . Turner *et al.* therefore teaches the claimed invention.” Applicants respectfully traverse this rejection.


Turner *et al.* does not disclose a nucleic acid sequence that comprises fragments or parts of the JHR/bHLH gene, which are suitable for isolation of the JHR/bHLH encoding nucleic acid sequence. Essentially, Turner *et al.* serves as a limited review of the juvenile hormone literature and provides, as described by Applicants in the instant specification, a rough genetic characterization and does not disclose the cloning, sequencing and expression of JHR/bHLH nucleic acid sequence or parts of a JHR/bHLH nucleic acid sequence. Claim 1 has been amended to claim the nucleic acid sequences which hybridize under stringent conditions with a polynucleotide having a nucleotide sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:6. This limitation was originally present in Claim 2, which was not rejected as anticipated by Turner *et al.* Since Claim 1 now incorporates the limitations of original Claim 2, it is therefore submitted that Turner *et al.* does not does not teach the invention as currently claimed in Claims 1, 7 and 8 and does not anticipate the currently pending claims of the present invention.

For at least the foregoing reasons, Applicants respectfully request reconsideration and removal of the rejections and allowance of Claims 1, 7, and 8.

Additionally, Claims 1-14, 18-29, and 42-51 were rejected under 35 U.S.C. §102(e) as being anticipated by Wilson *et al.*, U.S. Patent Number 6,326,165. The instant patent application claims priority to Wilson *et al.* under §120 as indicated in the new declaration attached herewith. Applicants submit that the perfected priority claim makes the rejection moot with respect to these claims, and respectfully requests consideration and removal of the rejections and allowance of Claims 1, 3-5, 7-14, 18-29, and 42-51.

For at least the foregoing reasons, Applicants respectfully request reconsideration and removal of the rejections and allowance of Claims 1, 3-5, 7-14, 18-29, 44-47, and 50-51. The foregoing is submitted as a full and complete Response to the Final Office Action mailed May 20, 2003. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account No. 19-5029. This Response places all claims in the present application in condition for allowance, and such action is courteously solicited. The Examiner is invited and encouraged to contact the undersigned attorney of record if such contact will facilitate an efficient examination and allowance of the application.

Respectfully submitted,

  
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